

ORAL ARGUMENT NOT YET SCHEDULED

Case No. 24-1188 and Consolidated Cases

**IN THE UNITED STATES COURT OF APPEALS
FOR THE D.C. CIRCUIT**

AMERICAN WATER WORKS ASSOCIATION, ET AL.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
Respondents.

On Petition for Review of Actions by Environmental Protection Agency

RESPONDENTS' MOTION FOR PARTIAL VACATUR

Dated: September 11, 2025

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INTRODUCTION

Last year, the U.S. Environmental Protection Agency (EPA) issued a rule under the Safe Drinking Water Act regulating six per- and polyfluoroalkyl substances (PFAS) as drinking water contaminants for the first time. “PFAS National Primary Drinking Water Regulation,” 89 Fed. Reg. 32532 (Apr. 26, 2024). EPA initially attempted to defend the Rule against forceful legal challenges raised in these petitions for review. Now, after further reviewing the statute pursuant to a publicly announced reconsideration process, EPA agrees with petitioners that parts of the rulemaking process were unlawful and parts of the Rule are thus invalid.

Consequently, EPA respectfully moves for partial vacatur of the Rule. First, EPA requests vacatur of its determination to regulate three PFAS individually—perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS), and hexafluoropropylene oxide dimer acid (HFPO-DA)—and to regulate mixtures of those three PFAS and a fourth PFAS, perfluorobutane sulfonic acid (PFBS), through a “hazard index” (collectively, the Index PFAS). Second, EPA requests vacatur of the Maximum Contaminant Level Goals (Goals) and Maximum Contaminant Levels (Standards) EPA set for those PFAS. As explained below, EPA does not seek vacatur of, and intends to defend, the portions of the Rule governing perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid

(PFOS) because the Agency's actions for those contaminants—in contrast to actions related to the Index PFAS—adhered to the statute's requirements.

The Act requires EPA to publish and seek comment on a preliminary regulatory determination for a contaminant *before* it may propose a national primary drinking water regulation that sets Goals and Standards for that contaminant. 42 U.S.C. § 300g-1(b)(1)(B)(ii), (iii). The Act further requires EPA to take final action on the preliminary regulatory determination before or at the same time as proposing the national primary drinking water regulation. *Id.* § 300g-1(b)(1)(E). For PFOA and PFOS, EPA followed the statutorily prescribed sequencing by proposing and finalizing a regulatory determination through notice and comment before proposing and finalizing a regulation through a further round of notice and comment. For the Index PFAS, however, EPA departed from the statutory scheme by proposing and finalizing a regulatory determination and regulation simultaneously and in tandem. Upon review, EPA acknowledges that its prior reading of the Act as authorizing such simultaneous promulgation, and defense of the Rule on this basis before this Court, were in error. EPA further acknowledges that this error denied the public and the regulated community the opportunity to adequately comment on and participate in the rulemaking process for the Index PFAS Goals and Standards with the benefit of the finalized regulatory determinations.

EPA has announced its plan to reconsider the regulatory determinations, Goals, and Standards for PFNA, PFHxS, HFPO-DA, and the Index PFAS, and thus seeks partial vacatur of the Rule to facilitate prompt judicial resolution of an important legal question that will affect its rulemaking. Prompt resolution is preferable to holding the case in abeyance. The key disputed issue is a pure question of law that can be resolved immediately, and finalizing a potential new rule under the cloud of a disputed legal issue would only lead to more litigation, burdening the Agency and this Court with needless additional proceedings.

Counsel for EPA has conferred with Counsel for all Petitioners and Respondent-Intervenors. Petitioners consent to this motion. Respondent-Intervenors oppose the motion and intend to file a response.

BACKGROUND

A. Statutory Background

The Safe Drinking Water Act authorizes EPA to evaluate drinking water contaminants and promulgate national primary drinking water regulations, which specify enforceable standards limiting contaminants in public water systems. As amended in 1996, the statute requires the Agency to take specific actions in a particular sequence meant to identify the universe of possible contaminants, select contaminants for regulation, and determine how to regulate the selected

contaminants. *See Nat. Res. Def. Council v. EPA*, 67 F.4th 397, 399 (D.C. Cir. 2023).

EPA must issue and regularly update a contaminant candidate list naming contaminants that are not yet regulated but occur or are anticipated to occur in public water systems. 42 U.S.C. § 300g-1(b)(1)(B)(i). EPA must determine whether to regulate at least five contaminants on the list every five years, although it may also propose to regulate a contaminant not included on the list when appropriate. *Id.* § 300g-1(b)(1)(B)(ii)(I), (III).

Next, the Act provides a specific process by which EPA can determine to regulate a new contaminant. *Id.* § 300g-1(b)(1)(B)(ii)(III). EPA must publish a preliminary determination and provide an opportunity for public comment before making its determination to regulate the contaminant. *Id.* § 300g-1(b)(1)(B)(ii), (iii). When making its final regulatory determination, EPA must determine that (i) “the contaminant may have an adverse effect on the health of persons;” (ii) “the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern;” and (iii) “in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.” *Id.* § 300g-1(b)(1)(A).

Finally, for each contaminant EPA decides to regulate, it must propose a Goal and a proposed national primary drinking water regulation that includes an appropriate Standard. *Id.* § 300g-1(a)(3), (b)(1)(A), (d). Goals are non-enforceable public health goals set at the level below which “no known or anticipated adverse effects” occur with an “adequate margin of safety.” *Id.* § 300g-1(b)(4)(A). The Standard generally must be set “as close to the [Goal] as is feasible.” *Id.* § 300g-1(b)(4)(B).¹

The Act imposes express limits on the sequencing of and deadlines for EPA’s regulatory determination and standard-setting processes. It states that EPA: “shall propose the [Goal] and national primary drinking water regulation [setting the Standard] for a contaminant not later than 24 months after the determination to regulate . . . , and may publish such *proposed* regulation concurrent with the determination to regulate.” *Id.* § 300g-1(b)(1)(E) (emphasis added). The Act thus requires, in addition to the iterative listing of candidate contaminants, sequencing: (1) a preliminary regulatory determination, a public comment period, and a final regulatory determination; and (2) a proposed substantive regulation no earlier than the *final* regulatory determination, a second public comment period, and then a final regulation. *Id.*

¹ The Act also requires EPA to consult with various federal entities and the Scientific Advisory Board at specific stages of the regulatory sequence. 42 U.S.C. § 300g-1(b)(1)(B)(i)(I), (d), (e).

B. Administrative Procedural Background

In 2020, EPA published in the Federal Register a preliminary determination to regulate PFOA and PFOS—both of which had previously been included on the contaminant candidate list—and solicited public comment. 85 Fed. Reg. 14098 (Mar. 10, 2020); 74 Fed. Reg. 51850 (Oct. 8, 2009); 81 Fed. Reg. 81099 (Nov. 17, 2016); 87 Fed. Reg. 68060 (Nov. 14, 2022). In March 2021, EPA published its final determination to regulate those chemicals. 86 Fed. Reg. 12272 (Mar. 3, 2021). This triggered the 24-month deadline for EPA to propose Goals and Standards for PFOA and PFOS. 42 U.S.C. § 300g-1(a)(3), (b)(1)(E).

In March 2023, EPA proposed the Rule challenged here. 88 Fed. Reg. 18638 (Mar. 29, 2023). This proposal included proposed Goals and Standards for PFOA and PFOS. *Id.* at 18666-68. At the same time, however, the proposed rule also introduced the Index PFAS into the rulemaking for the first time. In relevant part, the proposed rule included: (1) a preliminary determination to regulate the four Index PFAS both individually and as a mixture and (2) a proposed Goal and Standard applicable to the four Index PFAS as both a mixture and individually, using the hazard index approach. *Id.* at 18645-52, 18668-81, 18729-31. A hazard index is a mathematical formula used to account for the dose-additive effect of mixtures of contaminants with different toxicities where the mixtures may have

differing combinations of the contaminants and at differing concentrations. *Id.* at 18639.

In April 2024, EPA finalized the Rule challenged here. 89 Fed. Reg. 32532 (Apr. 2024). In the final Rule, EPA finalized the Goals and Standards for PFOA and PFOS. *Id.* at 32567, 32577. EPA also finalized individual regulatory determinations for three of the four Index PFAS—PFNA, PFHxS, and HFPO-DA—but not for PFBS. *Id.* at 32563. EPA finalized its regulatory determination for mixtures of all four Index PFAS (including PFBS). *Id.* at 32562-63. EPA also simultaneously finalized Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and (together with PFBS) for the four Index PFAS collectively as mixtures using a hazard index approach. *Id.* at 32571-73.

C. Litigation Procedural Background

In June 2024, Petitioners timely filed petitions for review of the Rule. ECF 2058535; ECF 2058848; ECF 2059361. On October 7, 2024, Petitioners filed their opening merits briefs, challenging EPA’s final Goals and Standards for PFOA and PFOS, EPA’s final regulatory determinations for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as a mixture, and EPA’s final Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as a mixture. ECF 2078734; ECF 2078731. EPA filed its combined response brief on December 23, 2024, defending all challenged portions of the Rule. ECF 2091318.

Respondent-Intervenors filed their brief on January 17, 2025, also defending the challenged portions of the Rule. ECF 2094834.

On January 20, 2025, a new Administration took office. On February 7, 2025, before Petitioners filed their reply briefs, EPA moved to put this matter in abeyance to allow the new Administration to consider the Rule. ECF 2099439. In May 2025, EPA announced that it intended to keep the current standards for PFOA and PFOS in place, adjust certain compliance deadlines, and intended to “reconsider the regulatory determinations for PFHxS, PFNA, HFPO-DA (commonly known as GenX), and the Hazard Index mixture of these three plus PFBS to ensure that the determinations and any resulting drinking water regulation follow the legal process laid out in the Safe Drinking Water Act.” May 14, 2025, EPA Press Release (available at: <https://www.epa.gov/newsreleases/epa-announces-it-will-keep-maximum-contaminant-levels-pfoa-pfos>). EPA has now determined that its decision to publish and seek comment on its proposed Goals and Standards for the Index PFAS (individually and as a mixture) simultaneously with EPA’s *preliminary* regulatory determination for those contaminants was inconsistent with the statute, and EPA no longer seeks to defend the relevant portions of the Rule and associated regulatory determinations on this basis. Ex. 1 (Browne Decl.).

STANDARD OF REVIEW

In reviewing EPA’s actions under the Act, this Court follows the Administrative Procedure Act’s standard of review. *City of Waukesha v. EPA*, 320 F.3d 228, 247 (D.C. Cir. 2003). Under that standard, the Court evaluates whether EPA’s action is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Int’l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (quoting 5 U.S.C. § 706(2)(A)). The Court reviews questions of statutory interpretation de novo. *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 991 (D.C. Cir. 2024). In deciding questions of statutory interpretation, “[c]ourts must exercise their independent judgment” to determine the “single, best meaning” of the statute, but “[c]areful attention to the judgment of the Executive Branch may help inform that inquiry.” *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412-13 (2024).

Where this Court has found EPA’s rules to be unlawful under the Act, it has vacated the relevant portions of the rulemaking. *See, e.g., Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1291 (D.C. Cir. 2000) (vacating EPA’s Goal for chloroform because it was “arbitrary and capricious and in excess of statutory authority”).

ARGUMENT

I. **EPA Lacks Statutory Authority to Propose a National Primary Drinking Water Regulation for a Contaminant Simultaneously with a Preliminary Regulatory Determination of that Contaminant.**

The Safe Drinking Water Act specifically requires the Agency to take a *seriatim* approach to regulation in which the Agency must first propose to regulate a particular drinking water contaminant and seek public comment on whether regulation is appropriate. 42 U.S.C. § 300g-1(b)(1)(E). Only *after* the public has had the opportunity to comment on that proposal and when EPA has finalized a determination to regulate may EPA publish a proposed regulation of that contaminant, either simultaneously with the final regulatory determination or after that final determination. *Id.*

Thus, the Act specifically requires two sequential public comment periods before a national primary drinking water regulation may be finalized. In the challenged actions, EPA interpreted the statute for the first time as authorizing the Agency to simultaneously publish a preliminary regulatory determination and a proposed regulation for public comment, and to simultaneously publish a final regulatory determination with a final regulation. *See* EPA Brief (ECF 2091318) at 29-37. EPA now acknowledges this reading was in error and inconsistent with the “single, best meaning” of the statute as informed by “all relevant interpretive tools.” *Loper Bright*, 603 U.S. at 400.

“The starting point for all questions of statutory interpretation is, of course, the plain language of the provisions at issue.” *Wash. Post v. Wash.-Balt. Newspaper Guild*, 787 F.2d 604, 606 (D.C. Cir. 1986). Here, the statute states that EPA “shall propose the [Goal] and [Standard] for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and may publish such *proposed* regulation concurrent with the determination to regulate.” 42 U.S.C. § 300g-1(b)(1)(E) (emphasis added). The best reading of this provision is that the soonest EPA may publish a proposed regulation is with the *final* regulatory determination, not with the preliminary regulation.

Significantly, “determination to regulate” appears twice in this statutory provision. The first occurrence explicitly cross-references “the determination to regulate under subparagraph (B)” of section 300g-1. Subparagraph (B) indisputably sets forth the specific steps EPA must take when issuing the *final* “determination to regulate.” *Id.* § 300g-1(b)(1)(B)(ii); *see* EPA Brief (ECF 2091318) at 30. One of the intermediate steps subparagraph (B) identifies in the progression to the “determination to regulate” is providing “notice of the *preliminary* determination and opportunity for public comment . . .” 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I) (emphasis added). Because the reference to the “preliminary determination” is a step necessary to the “determination to regulate,” the only valid

reading of “the determination to regulate under subparagraph (B)” is that it is the final determination.

In its second usage of “determination to regulate” in the Act’s provision sequencing the regulatory determination and the regulation, the statute provides that EPA “may publish [a] proposed regulation concurrent with the determination to regulate.” *Id.* § 300g-1(b)(1)(E). Despite no meaningful distinction in the language between the two clauses, EPA previously argued that this second usage of “determination to regulate” refers to a preliminary regulatory determination rather than a final regulatory determination. EPA Brief (ECF 2091318) at 30. EPA now acknowledges that the best reading of the statute is one in which this same phrase is given the same meaning throughout the statutory provision. *See, e.g., Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 821-22 (2024) (rejecting the argument that “the same words . . . in a single statute should mean different things in different contexts . . .” (emphasis in original)); *Clark v. Martinez*, 543 U.S. 371, 378 (2005) (“To give these same words a different meaning for each category would be to invent a statute rather than interpret one.”).

Critically, the statute uses the precise term “determination to regulate” *only* to refer to the final determination. *See, e.g.,* 42 U.S.C. § 300g-1(b)(1)(B)(ii), (b)(1)(E). The statute only refers to “determination to regulate” in subsections 300g-1(b)(1)(B) when outlining the steps necessary for the final regulatory

determination and in subsection 300g-1(b)(1)(E) when setting forth the sequencing of the final regulatory determination and the regulation.

Subsection 300g-1(b)(1)(B)(ii)(I) states that, after receiving public comments, EPA shall make “determinations of whether or not to regulate [particular] contaminants.” Because these determinations are made after notice and comment are completed, it is clear from the context that determinations referred to here are final determinations, though they may be determinations either for or against regulation. Subsection 300g-1(b)(1)(B)(ii)(II) and (III) then use the term “determination to regulate a contaminant” to refer to a final determination—not a preliminary determination—that the statutory criteria are satisfied and that regulation is warranted. Finally, subsection 300g-1(b)(1)(B)(ii)(IV) states that “[a] determination under this clause not to regulate a [particular] contaminant shall be considered final agency action and subject to judicial review.” That provision, too, refers to a final determination, made after the Agency has considered public comments, that a particular contaminant should *not* be regulated.

Although EPA previously argued that the statute’s use of the term “determination” to refer to a preliminary determination elsewhere in the statute demonstrates that second usage of “determination” in subsection 300g-1(b)(1)(E) could refer to a preliminary determination, EPA Brief (ECF 2091318) at 30 (citing 42 U.S.C. § 300g-1(b)(1)(B)(iii)), upon further analysis EPA acknowledges the

context of that provision obviates the need for the word “preliminary.” Because § 300g-1(b)(1)(B)(iii) specifically addresses the requirement for public comment on “the determination,” the context makes clear that it refers to a preliminary determination without requiring the specific term “preliminary.” Moreover, this provision refers to a “determination” put out for public comment; it does not use the specific term “determination to regulate” at issue subsection 300g-1(b)(1)(E).

In short, although section 300g-1 sometimes uses the term “determination” to refer to a preliminary determination, it uses the specific phrase “determination to regulate” (as well as the phrase “determination under this clause not to regulate”) and the umbrella phrase “determinations of whether or not to regulate”) only to refer to the final determinations that EPA makes after completing notice and comment on the preliminary determination. Because courts “generally presume differences in language . . . convey differences in meaning,” *Rudisill v. McDonough*, 601 U.S. 294, 308 (2024), Congress’s specific use of “determination to regulate” should be construed to refer to the final determination to regulate here.

Upon further analysis, EPA’s prior argument relying on the term “publish” to interpret the second usage of “determination to regulate” in subsection 300g-1(b)(1)(E) as a preliminary determination was similarly erroneous. *See* EPA Br. (ECF 2091318) at 31. Nothing in the text of the Act suggests that final regulatory

determinations do not need to be “publish[ed],” and thus nothing suggests that this verb may *only* be used in relation to preliminary regulatory determinations.

Additionally, further careful analysis of this subsection demonstrates that reading the second usage of “determination to regulate” as the *final* determination is the only reading that gives independent meaning to this phrase when considered as part of subsection 300g-1(b)(1)(E) as a whole. *Agnew v. Gov’t of Dist. of Columbia*, 920 F.3d 49, 57 (D.C. Cir. 2019) (“a statute [should] not be interpreted in a way that renders any part of it superfluous”); *NASDAQ Stock Market LLC v. SEC*, 961 F.3d 421, 426 (D.C. Cir. 2020) (explaining a “statutory interpretation must account for both the specific context in which the language is used and the broader context of the statute as a whole” (internal quotations omitted)); *contra* EPA Brief (ECF 2091318) at 31-32. The best reading of subsection 300g-1(b)(1)(E) demonstrates that it provides a very specific window in which a regulation may be proposed. The first usage of subsection 300g-1(b)(1)(E) provides that the *latest* EPA can propose a regulation is 24 months after a final regulatory determination. The second usage provides that the *earliest* EPA can propose a regulation is concurrent with a final regulatory determination. Put differently, the statute provides that EPA has exactly 24 months to propose a regulation starting from the date the final regulatory determination is published. EPA’s prior reading failed to give full effect to this statutorily prescribed window.

Finally, reading both the first and second usages of “determination to regulate” as referring to the final regulatory determination effectuates Congress’s goal in the 1996 amendments to the Act. *Contra* EPA Brief (ECF 2091318) at 33. This reading maintains EPA’s deadline to propose a regulation within 24 months of the final regulatory determination, while also maintaining Congress’s commitment to ensuring EPA’s ultimate regulation benefits from substantial and varied external input. *See, e.g.*, 42 U.S.C. § 300g-1(b)(1)(B)(ii), (b)(1)(B)(iii), (b)(3)(C), (b)(6)(A), (e). Thus, the provision accelerates the rulemaking process while ensuring that the resulting regulation affords the public and regulated entities multiple rounds of opportunity to inform its analysis and contents.

Accordingly, EPA acknowledges that it misread the statute when interpreting it as allowing EPA to publish a final regulatory determination concurrently with a final regulation. EPA further acknowledges that it erred when it published the final regulatory determinations concurrently with the final regulation setting the Goals and Standards for PFNA, PFHxS, and HFPO-DA individually, and the four Index PFAS as a mixture.

II. EPA Waives the Harmless Error Defense.

Harmless error is a waivable defense. *See, e.g., Arej v. Sessions*, 852 F.3d 665, 669 (7th Cir. 2017) (Sykes, J. concurring) (noting government waived harmless error defense in petition for review of immigration removal decision);

Keller v. Berryhill, 754 F. App'x 193, 199 (4th Cir. Nov. 29, 2018) (holding Social Security Administration waived harmless-error defense by failing to raise it in appeal); *Keck v. O'Malley*, No. 22-1716, 2024 WL 3935441, at *4 (7th Cir. Aug. 26, 2024) (Kirsch, J. concurring) (same). EPA withdraws the portion of its opening brief in which it asserted the harmless error defense for both the final regulatory determination and the Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS. *See* EPA Brief (ECF 2091318) at 36-38. Because EPA has waived this defense, the Court should vacate both the regulatory determination and the Goals and Standards for these PFAS.

III. In the Alternative, the Error Was Not Harmless as to the Goals and Standards.

Contrary to its original position, EPA now recognizes that its publication of the final regulation concurrently with the final Goals and Standards for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as a mixture was not harmless. The burden to demonstrate harm in this context is low. *See Sprint Corp. v. FCC*, 315 F.3d 369, 377 (D.C. Cir. 2003) (holding that “a showing of actual prejudice [was] not required under the prejudicial error rule” when the agency had “failed to issue a new NPRM to afford proper notice and opportunity for comment”); *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1324 (D.C. Cir. 1988) (placing burden to establish prejudice on petitioner is inappropriate

when the agency “completely failed” to comply with relevant procedural requirements).

Here, EPA did solicit public comments on the proposed regulatory determinations, and on the proposed Goals and Standards. But the statute specifically requires EPA to afford the public two *sequential* opportunities to comment: first on whether or not to regulate a contaminant and then, once the public knows the basis and outcome of the final regulatory determination, on the proposed regulation. 42 U.S.C. § 300g-1(b)(1)(E). EPA both entirely failed to provide the public with the separate, sequential public comment period for the Goals and Standards, and failed to allow the public to comment on the proposed Goals and Standards with the benefit of the outcome and basis for the final regulatory determination.

Notably, the preliminary and final regulatory determinations were markedly different. The preliminary determination proposed to regulate all four Index PFAS—PFNA, PFHxS, HFPO-DA, *and* PFBS—as mixtures and, because the mixture in the proposal could contain only one contaminant, also individually. 88 Fed. Reg. at 18638, 18668, 18671. The final regulatory determination, however, only determined to regulate three of the Index PFAS—PFNA, PFHxS, and HFPO-DA—individually, but still determined to regulate mixtures of PFNA, PFHxS, HFPO-DA, *and* PFBS. In so doing, EPA deprived the public of an adequate

opportunity to comment on the Goals and regulations setting the Standards with the statutorily mandated benefit of the final regulatory determination.

There are any number of ways the public could have commented on the proposed regulation had they had full knowledge of the regulatory determination at the appropriate time, and EPA cannot speculate as to the full extent of the harm this error has caused. *See, e.g., City of Waukesha*, 320 F.3d at 246 (petitioners need not always show “what additional comments they would have submitted had notice been adequate” in order to establish prejudice); *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002) (petitioners “need not . . . indicate[] additional considerations they would have raised in a comment procedure”).

Had EPA finalized the regulatory determinations for mixtures of the Index PFAS before or concurrent with issuance of proposed Goals and Standards, then the public’s comments on the proposed rule could have accounted for the Agency’s decision to regulate PFBS as part of mixture but not individually. Because of this error, the public lacked the opportunity to comment on EPA’s proposal with the certainty of the final regulatory determinations. Accordingly, this error fatally infected the Goals and Standards for PFNA, PFHxS, HFPO-DA, and the Index PFAS.

IV. Vacatur of the Regulatory Determinations and Regulations for PFNA, PFHxS, HFPO-DA, and the Index PFAS Is Appropriate.

In reviewing whether to vacate a rule under the Safe Drinking Water Act, this Court applies the two-part test set forth in *Allied-Signal, Inc. v. Nuclear Regulatory Commission*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). *See Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1273 (D.C. Cir. 1994). “The decision whether to vacate depends on ‘the seriousness of the order’s deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed.’” *Allied-Signal*, 988 F.2d at 150-51 (internal quotations omitted).

The first *Allied Signal* prong, concerned with the seriousness of the alleged agency error, weighs the extent to which the agency can correct the error on remand. *See Standing Rock Sioux Tribe v. U.S. Army Corps of Eng’rs*, 985 F.3d 1032, 1051 (D.C. Cir. 2021). Here, where the Agency must essentially restart the regulatory process, including taking two new rounds of public comment and considering those comments, the “extent of doubt whether the agency chose correctly” is substantial. *Allied-Signal*, 988 F.2d at 150-51.

Additionally, leaving the Rule in place could actually inhibit EPA from meaningfully considering public comment and addressing that comment in a new rule. Pursuant to this Court’s precedent, EPA cannot rescind a regulatory determination based on additional data or analysis. *Nat. Res. Def. Council*, 67

F.4th at 405. Moreover, it cannot revise a regulation without “maintain[ing], or provid[ing] for greater, protection of the health of persons.” 42 U.S.C. § 300g-1(b)(9). This is particularly problematic where the public lost first the opportunity to focus exclusively on whether or not EPA should regulate the Index PFAS (individually and/or as a mixture), and then a second, subsequent opportunity to separately focus exclusively on the manner in which EPA should regulate the Index PFAS (individually and/or as a mixture). Moreover, the public did not have the opportunity to comment on the Goals and Standards for PFNA, PFHxS, HFPO-DA, or the Index PFAS as a mixture with the certainty of final regulatory determinations. The public should have the benefit of these comment periods and EPA should be able to consider all public comments to assess whether to make a new regulatory determination and, if necessary, set the Goals and Standards appropriately.

The second prong—the potentially disruptive effects of vacatur—similarly weigh in favor of vacatur. Here, vacatur of the regulatory determinations and the Goals and Standards for PFNA, PFHxS, HFPO-DA, and the Index PFAS would not cause “the disruptive consequences of an interim change that may itself be changed.” *Allied-Signal*, 988 F.2d at 150-51. The first deadline (an initial monitoring deadline) for these contaminants is April 26, 2027, so obligated parties are not yet subject to requirements that would change with vacatur of the Rule. 40

C.F.R. § 141.902(b)(1)(xi). Moreover, in the absence of vacatur, obligated parties could eventually be forced to comply with regulations that may ultimately change and are, in EPA's view, unlawful under the statute.

In sum, the Court should vacate the portion of the Rule finalizing regulatory determinations and regulations for PFNA, PFHxS, and HFPO-DA individually and the Index PFAS as mixtures.

CONCLUSION

For the foregoing reasons, the Court should grant EPA's motion to partially vacate the Rule. EPA will identify those portions of its previously filed brief it no longer advances at an appropriate time.

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Respectfully submitted,

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